REMARKS

The title has been amended to remove the objection raised by the Examiner. Claims 160 and 187 have been amended. Claims 160-162, 165, and 187-190 are currently pending. Reconsideration of the application is respectfully requested in view of the following remarks.

Interview Summary

Applicant wishes to thank Examiners Hui, Jiang, and Padmanabhan for the courtesies extended to Applicant's attorneys, Dr. Anie Roche and Albert Halluin, and licensee's officers Ms. Joanne Leonard and Dr. Cynthia Robinson on November 3, 2005.

I. Specification Objection

The Examiner objected to the instant specification under 37 C.F.R. 1.77, as to the amended title filed on March 14, 2005 wherein the title was amended to read, "Dehydroepiandrosterone Compositions and Formulations for Treating Respiratory Diseases." According to the Examiner, "the new title is deemed to insert new matter into the specification since the specification as originally filed does not provide support for "Treating Respiratory Diseases." The Applicant has amended the title and hence, Applicant believes that the objection is now moot.

II. Claim Rejections Under 35 U.S.C. 102(b)

The Examiner rejected claims 187-188 under 35 U.S.C. 102(b) as being anticipated by GB 2240472. According to the Examiner, "GB 2240472 discloses a composition comprising dehydroepiandrosterones (DHEA) herein in a particle size less than 10 μm. Thus, the particle size, less than 10 μm, reads on about 10 μm, as instantly claimed."

Applicant traverses this rejection. However, to expedite prosecution, Applicant has amended claim 187 to include particle ranges from 15 μm to about 500 μm in size. Applicant respectfully requests withdrawal of the rejection.

III. Claim Rejections Under 35 U.S.C. 103(a)

The Examiner rejected claims 160-162, 165, and 187-189 under 35 U.S.C. 103(a) as being unpatentable over Pendergast (4,956,355 of record) in view of Lieberman, et al. (Pharmaceutical

Dosage Forms, page 110, of record) and "Remington: The Science and Practice of Pharmacy, 17th Ed, by Alfonso R. Gennaro, 1985, page 1505 (PTO-892).

The Examiner also rejected claims 160, 165, and 187-180 under 35 U.S.C. 103(a) as being unpatentable over Nyce (5,527,789, of record) in view of Lieberman, et al. (Pharmaceutical Dosage Forms, page 110) and "Remington: The Science and Practice of Pharmacy," 17th Ed, by Alfonso R. Gennara, 1985, page 1505 (PTO-892).

Both of these rejections are improper as noted below in the following remarks.

The Examiner has cited Pendergast and Nyce as disclosing DHEA and DHEA-S as compositions of matter. The Examiner combines Pendergast and Nyce, with basic Pharmacy textbooks, which disclose numerous possible routes of administration of drugs along with the various formulation types that can be used. There is no motivation other than improper hindsight for combining these references and picking and choosing from among the many modes of administration disclosed by Remington and there is no expectation for success for such a combination. The Examiner asserts that it would have been obvious to utilize inhalation as the route of administration.

While inhalation has become a more common mode of drug formulation in recent years for treating asthma, this was not the case 10 years ago. The instant application enjoys a priority pf 1995, and the prior art of knowledge must be evaluated based on what was known in 1995, not 2005. The prior art cited does not teach that inhalation of DHEA-S as the mode of choice. Even under the present time frame, there are many aspects of drug delivery that are unpredictable. It is not a simple matter to change from one route of administration to another and expect interchangeability and success. During the interview, it was pointed out that the DHEA-S compound was superior to DHEA in an inhaled formulation. The Examiners were shown data supporting this point. This further points to the unpredictability of compositions used as inhalants.

While the primary references cited include many modes of administrations. This alone does not negate the claimed compositions as being unpatentable. It is possible for a prior art reference to include a wide variety of species, but not to disclose a particular subject matter, as here claimed. The legal question is: Whether or not it can be fairly and reasonably said that one of ordinary skill in

this art through a reading of the entire reference has constructive possession of the claimed composition itself, as opposed to the possession of mere language which somehow embraces the name of what may be claimed. See In re Lavisi et al., 144 USPQ 646 at page 650.

The Examiner has seemingly recognized the shortcomings of the primary references and relies upon Remington to bridge the gap. This combination is improper and uses improper hindsight.

It is well established patent law that "(i)t is impermissible within the framework of that Section 103 to pick and choose from one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. "In re Wesslau, 353 F.2d 238, 147 USPQ 391. While it may be possible as an abstract proposition to select inhalation formulations from Remington, as the Examiner has done, to arrive at Applicant's claimed invention, there is simply no basis for making such a combination based on the prior art relied upon by the Examiner. Only Applicant's specification and claims suggest reasons for such a combination, and under the provisions of 35 USC Section 103 that is impermissible. See Ex parte Fleishman, 157 USPQ 155, Ex parte Henderson, 176 USPQ 142 (1972), and In re Civitello, 144 USPQ 10 (1964).

Applicant has provided an expert declaration based on her scientific experience stating that it was unexpected that the respirable DHEA-S produces an unexpectedly low systemic absorption without systemic side-effects. Dr. Robinson avers that she would have expected that greater access to the systemic circulation in the lungs would cause systemic absorption and result in side effects such as modified levels of sex hormones and/or adverse effects on the sex organs. Unexpectedly, minimal systemic side effects were observed. The Examiner has not addressed the unexpected results described in the declaration. The references cited by the Examiner does not clearly establish that the results are expected. The declaration shows an almost elimination of the side effects that the expert avers would not have been expected. This represents a difference in kind, not degree, and thus shows unexpected results. The Examiner has not refuted the expert opinion of Dr. Robinson with any facts or evidence.

The MPEP in section 2144.08 IIA4(e) provides that the predictability of the technology needs to be considered. There is case law that supports that "a considerable degree of

unpredictability" in a field allows for a decision in favor of patentability. See In re Schechter 205 F. 2d 185,191 (CCPA 1953). In In re Schechter, the court reversed a rejection of unpatentability to a group of compounds over prior art isomers. The court took biological function into account in deciding in favor of patentability. The court held that "there is a considerable degree of unpredictability in the insecticide field with homologs, isomers, and analogs of known effective insecticides have proven ineffective as insecticides." In view of this unpredictability, the court found the group of compounds inventive and patentable. Applicant would like to assert that it is unexpected that an inhalable formulation of a DHEA compound would be effective in the treatment of asthma with low side effects due to the unpredictability in the field of inhalable formulations. There are many different variables in the development of an effective inhalable formulation for a particular drug. Thus, although inhalable formulations have been developed since about 1956, this field is still an unpredicatble field. See Smyth paper. For example, Symth lists some of the factors to be considered in the formulation of a propellant-driven metered dose inhaler, including for example, the various types of propellants used, formulation strategies, e.g., solution vs. suspension, and device characteristics. In the manufacture of powder delivery devices, the success of the formulation depends on the powder production process, the formulation, and the inhaler device. See Chan and Chew paper. Another publication by Cochrane et al., describes the different factors that affect the inhaled route of administration of inhaled corticosteroids. The authors point that the factors that affect the amount of drug delivered to the lung include inhaler technique, inhaler type, fine particle does, and particle distribution. The authors also discuss that lung deposition depends on particle dynamics and jet flow, which vary with drug formulation, inhaler type, and patient inhaler technique. Thus, even for corticosteroids, a commonly used drug via inhalation, there are many considerations before achieving a successful formulation. Due to all these variables, Applicant would like to reiterate that the field of inhalable formulation is an unpredictable field and that there is no expectation of success, and hence, the Applicant's claims are non-obvious.

III. Double Patenting

For the record, Applicant is filing herewith a terminal disclaimer with respect to U.S. Patent No. 6,087,351. This commonly assigned patent is a parent of the present application, and includes claims for the treatment of asthma with DHEA type compounds.

CONCLUSION

In light of the remarks set forth above, Applicant believes that they are entitled to a letters patent. Applicant respectfully solicits the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any question, the Examiner is encouraged to telephone the undersigned.

Respectfully submitted,

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